REMARKS

Applicants respectfully request reconsideration of the application in view of the foregoing amendments and the following remarks.

Claim Status

Claim 1-9, 11-22 and 24-27 are amended. Support for these amendments is found throughout the application as filed, including in the original claims and paragraphs [0001], [0002], [0024], [0035] and [0041]. Thus, no new matter is added. Claim 10 is canceled. These amendments are made without prejudice or disclaimer and Applicants reserve the right to pursue any non-elected subject matter in one or more continuing applications with the same priority rights as the instant application. Upon entry of the amendments, claims 1-9, 11-22 and 24-27 will remain pending in the application, and it is these claims that are presented for reconsideration.

Claim Objections

The claims were objected to for alleged informalities in the preamble, the use of plus signs (+), and the capitalization of certain active substance names. The instant amendments are believed to overcome these objections.

Rejections under 35 U.S.C. § 112, first paragraph

Claim 7 was rejected for alleged lack of enablement and written description with respect to the recitation of "inorganic salts." Without acquiescing to the propriety of these rejections, Applicants amend claim 7 to recite "mineral salts approved for human consumption." Support for this language is found, for example, in paragraph [0035] of the application as filed.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 6-7, 9, 13, 22, and 24 were rejected for alleged indefiniteness for the reasons set forth at pages 3-4 of the Office Action. These rejections are addressed in turn below.

A. Claims 6 and 24 were rejected for the recitation of parenthetical entries. The foregoing amendments obviate these rejections.

B. Claims 9, 13, and 24 were rejected for reciting the term "derivative." Applicants respectfully traverse the Examiner's position that these claim terms are indefinite. To the contrary, the terms at issue are well known to those skilled in the art, and thus need not be further defined or explained in the specification. As explained in *Space Systems/Loral, Inc., v. Lockheed Martin Co.*, 405 F.3d 985 (Fed. Cir. 2005), the specification need not include information that is already known and available to the experienced public.

> Claim 9 recites that the diluent may be a "starch derivative." Starch derivatives suitable as diluents in pharmaceutical compositions are well known to the skilled artisan. For example, a Wikipedia search (attached), identifies glucose, dextrose, maltodextrin, and various corn syrups as exemplary starch derivatives. Thus, there is no indefiniteness in the recitation of a "starch derivative" in claim 9.
>
> Claim 13 recites "terpene derivatives," which are expressly exemplified in the specification. For example, paragraph [0046] discloses illustrative terpene derivates, including but not limited to eugenol, geraniol, nerol, eucalyptol, and menthol. Thus, there is no indefiniteness surrounding the meaning of "terpene derivative" in claim 13.
>
> Claim 24 recites "natural estradiol derivative[s]," which also are well known in the art. For example, US 2004/0110732 (filed March 20; 2003 and published June 10, 2004), at paragraphs [0012]-[0014] discloses derivatives of natural estradiol such as ester derivatives, exemplified by estradiol valerate, and derivatives that are derived from the estrane ring system of estradiol, such as ethinylestradiol. Thus, there is no indefiniteness in the recitation of a "natural estradiol derivative" in claim 24.

C. Claim 9 was rejected for reciting "a dextrose excipient." Without acquiescing to the propriety of this rejection, Applicants amend claim 9 to recite "a dextrose."

D. Claim 13 is rejected for reciting "a component of an essential oil." Again, this term is not indefinite because components of essential oils that are useful as absorption enhancers are well-known in the art. For example, Siafy et al., *Pak J. Pharm. Sci.* 13: 29-32 (2000) (abstract attached), describes the activity of cineole, a eucalyptus oil component, as an absorption enhancer. *See also* Williams & Barry, *Pharm. Res.* 8: 17-24 (1991) (abstract attached)(absorption enhancing activity of ascaridole, a component of the essential oil chenopodium).

E. Claim 22 was rejected for allegedly failing to state the claimed limitation. The amendments to claim 22 obviate this rejection.

In view of the foregoing, Applicants believe that the instant claims fully comply with the requirements of §112, second paragraph, and respectfully urge reconsideration and withdrawal of these rejections.

Rejections under 35 U.S.C. § 102

A. Rejection over Geyer *et al.*

Claims 1-3, 5-6, 8-10, 12-18, and 25-26 were rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Geyer et al. Office Action, pages 4-6. Applicants respectfully traverse this rejection.

Instant claim 1 (from which the other rejected claims depend) recites an immediate-release pharmaceutical or nutraceutical micronized powder having a particle size of at most 100 μm and comprising (a) at least one active substance; (b) at least one wetting agent; (c) at least one diluent; and (d) an antistatic agent comprising from 0.01 % to 10% by weight of the

total weight of the composition, wherein the powder has a dissolution kinetic of less than 30 seconds in an aqueous medium at pH 5 to 9. Geyer does not teach such a powder.

Geyer is directed to a chewable composition that masks the unpleasant taste of certain drugs. There is no indication that Geyer's composition is an "immediate-release" powder according to the present invention, *e.g.*, that it has a dissolution kinetic of less than 30 seconds in an aqueous medium. While Geyer states that its composition "disintegrates rapidly in the mouth," there is no further explanation of this property, let alone any data indicating that the powder releases all of the active substance within 30 seconds. Indeed, the purpose of Geyer is to provide a composition that disperses "*when chewed*," *see* Geyer, column 4, lines 49-50 (emphasis added), which is quite different from the immediate release of the present invention, which occurs upon contact with mucosa.

Moreover, Geyer does not teach or suggest a powder comprising an antistatic agent that comprises from 0.01 % to 10% by weight of the total weight of the composition, as claimed.

Because Geyer does not teach a powder meeting every limitation of the instant claims, the §102 rejection over Geyer should be withdrawn.

B. Rejection over Stamm *et al.*

Claims 1-3, 5, 7, 9-13, 18-19, and 26-27 are rejected under 35 U.S.C. § 102 (b) as allegedly anticipated by Stamm *et al.* Office Action, pages 6-7. Applicants respectfully traverse this rejection.

Stamm is directed to a fenofibrate composition for oral administration, *e.g.*, for delivery through the gastrointestinal tract. Like Geyer, Stamm does not teach a powder that possesses the properties recited in the instant claims. Although Stamm describes its product as an "immediate-release" formulation, Stamm's product does not exhibit the dissolution kinetic recited in the instant claims. As shown in Figure 1 of Stamm, it took 30 *minutes* for

Stamm's product to reach 95% dissolution in an aqueous medium. This is far beyond the 30 second dissolution kinetic recited in the instant claims.

Moreover, Stamm does not teach or suggest a powder comprising an antistatic agent that comprises from 0.01 % to 10% by weight of the total weight of the composition, as claimed. Although Stamm states that its compositions can include any number of excipients, and mentions colloidal silica and talc in a laundry list of such optional components, it does not teach or suggest any advantage of including an antistatic agent in its composition, and certainly does not provide any teaching, suggestion, or guidance that would lead a skilled artisan to include 0.01 % to 10% by weight of an antistatic agent.

Because Stamm does not teach a powder meeting every limitation of the instant claims, the §102 rejection over Stamm should be withdrawn.

Rejections under 35 U.S.C. § 103

A. Rejection over Ohno *et al.* in view of Geyer *et al.*

Claims 4, 7, 11, and 19 were rejected under 35 U.S.C. § 103 (a) as allegedly obvious in view of Ohno *et al.* and Geyer *et al.* Office Action, pages 7-8. Applicants respectfully traverse this rejection.

The inability of Geyer to teach the present invention is demonstrated above. Although Ohno is directed to pharmaceutical compositions for buccal disintegration/dissolution, the combination of Ohno and Geyer does not suggest the claimed powder.

For example, the combination of references does not suggest a powder comprising an antistatic agent that comprises from 0.01 % to 10% by weight of the total weight of the composition, as claimed. Although Ohno states that its compositions can include a number of excipients, and mentions the use of talc as a lubricant, it does not teach or suggest any advantages of including an antistatic agent in its composition, and certainly does not provide

any teaching, suggestion, or guidance that would lead a skilled artisan to include 0.01 % to 10% by weight of an antistatic agent.

Because even the combination of Geyer and Ohno fails to suggest the claimed invention as a whole, the §103 rejection is improper and should be withdrawn.

B. Rejection over Geyer *et al.* in view of McCarty

Claims 4, 7, 11, and 24 were rejected under 35 U.S.C. § 103 (a) as allegedly obvious in view of Geyer *et al.* and McCarty. Office Action, pages 8-10. Applicants respectfully traverse this rejection.

The inability of Geyer to teach the present invention is demonstrated above. Although McCarty is directed to pharmaceutical compositions for buccal administration, the combination of McCarty and Geyer does not suggest the claimed powder.

For example, the combination of references does not suggest a powder comprising an antistatic agent that comprises from 0.01 % to 10% by weight of the total weight of the composition, as claimed. Indeed, neither Geyer nor McCarty teach or suggest the use of an antistatic agent, or the use of any of the specific antistatic agents recited in claim 11. Thus, the combination of Geyer and McCarty fails to suggest the claimed invention as a whole, and the §103 rejection should be withdrawn.

C. Rejection over Geyer *et al.* in view of Mundt

Claims 20-22 were rejected under 35 U.S.C. § 103 (a) as allegedly obvious in view of Geyer and Mundt. Office Action, pages 10-11. Applicants respectfully traverse this rejection.

This rejection relies on Geyer as the primary reference, and cites Mundt for teaching packaging materials. As shown above, however, Geyer does not teach or suggest a powder in accordance with the present invention. The combination of Geyer and Mundt cannot render the present invention obvious, therefore, and so the §103 rejection should be withdrawn.

CONCLUSION

Applicants believe that the application is in condition for allowance, and an early notice to that effect is earnestly solicited.

Should there be any questions concerning this application, or should any issues remain, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,

Date April 27, 2007

By Courtenay Brinckerhoff

FOLEY & LARDNER LLP
Customer No. 22428
Telephone: (202) 295-4094
Facsimile: (202) 672-5399

Courtenay C. Brinckerhoff
Attorney for Applicant
Registration No. 37,288

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